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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,846

04/21/2006

Jadwiga Bienkowska

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EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

06/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,846	<b>Applicant(s)</b> BIENKOWSKA ET AL.	
	<b>Examiner</b> QUANG NGUYEN, Ph.D.	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42-56 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 42-56 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Claims 42-56 are pending in the present application, and they are subjected to the following restrictions.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 42-43, 49 and 52, drawn to a composition of matter comprising an isolated polypeptide in a), b), c) or d) having fibulin-like activity; active conjugates or complexes thereof; a peptide mimetic thereof; a polypeptide in n); and the first method of treating a disease needing an increase in the fibulin-like activity using the same.

Group 2, claims 42-43 and 44, drawn to a composition of matter comprising a fusion protein e); active conjugates or complexes thereof.

Group 3, claims 42-43, 49 and 53, drawn to a composition of matter comprising an antagonist of a polypeptide in a), b), c) or d); and the first method of treatment using an effective amount of an antagonist.

Group 4, claims 42-43, 45-46 and 48, drawn to a composition of matter comprising a ligand which binds specifically to a polypeptide a), b), c) or d); and the first method for determining the activity and/or the presence of a fibulin-like polypeptide in a sample using the same ligand.

Group 5, claims 42-43, 47 and 49-51, drawn to a composition of matter comprising an isolated nucleic acid encoding a polypeptide set forth in a), b), c) or d); an isolated nucleic acid sequence in k), l); a vector in m) and a host cell in o); and the first method of expressing or making a polypeptide using the same.

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Group 6, claims 42-43 and 49-51, drawn to a composition of matter comprising an isolated nucleic acid encoding a fusion protein of a polypeptide in a), b), c) or d); and the first method of expressing or making the fusion protein.

Group 7, claims 42-43, drawn to a composition of matter comprising an isolated nucleic acid encoding an antagonist of a polypeptide in a), b), c) or d).

Group 8, claims 42-43, 49 and 54, drawn to a composition of matter comprising a transgenic animal cell or a transgenic non-human animal having enhanced expression level of a polypeptide set forth in a), b), c) or d); and the first method of use for screening candidate compounds effective to treat a disease related to the fibulin-like polypeptides.

Group 9, claims 42-43, 49 and 54, drawn to a composition of matter comprising a transgenic animal cell or a transgenic non-human animal having reduced expression level of a polypeptide set forth in a), b), c) or d); and the first method of use for screening candidate compounds effective to treat a disease related to the fibulin-like polypeptides.

Group 10, claims 42-43, 49 and 52, drawn to a compound that enhances the expression level of a polypeptide set forth in a), b), c) or d), without knowing exactly what the structure of the compound to be; and the first method for treating a disease needing an increase in the fibulin-like activity using the same compound.

Group 11, claims 42-43, 49 and 53, drawn to a compound that reduces the expression level of a polypeptide set forth in a), b), c) or d), without knowing exactly what the structure of the compound to be; and the first method of use for treatment using the same.

Group 12, claims 49 and 52, drawn to a second method of use for treating a disease needing an increase in the fibulin-like activity using a nucleic acid of the present invention.

Group 13, claims 49 and 52, drawn to a third method of use for treating a disease needing an increase in the fibulin-like activity using a genetically modified cell of the present invention.

Group 14, claims 49 and 53, drawn to a second method of use for treating a disease using an effective amount of a ligand of the present invention.

Group 15, claims 49 and 54, drawn to a fourth method of use for screening candidate compounds effective to treat a disease related to the fibulin-like polypeptides using a cell of the present invention.

Group 16, claims 49 and 55, drawn to a second method of use for identifying a candidate compound as an antagonist/inhibitor or agonist/activator of a fibulin-like polypeptide using the polypeptide of the present invention.

Group 17, claims 49 and 56, drawn to a third method of use for determining the presence or the amount of a transcript or of a nucleic acid encoding a fibulin-like polypeptide in a sample using the nucleic acid of the present invention.

The currently claimed subject matter (Inventions of Groups 1-17) lacks unity of invention according to Rule 13.1 PCT for the following reasons.

The compositions in Groups 1-11 differ one from the others because they are structurally, physically and chemically different one from the others, as well as they have different properties. For example, the compositions in Groups 1-4 are made up of amino acid residues, while the compositions in Groups 5-7 are composed of nucleotides, the compositions of Groups 8-9 are living entities that are physically different from other compositions. With respect to the compositions in Groups 10-11, drawn to compounds that have opposite properties (enhancing vs reducing expressing level of a polypeptide of the present invention) with unknown structure that may not share the same structural features as any of the other compositions. The composition of Group I does not require the presence of a protein sequences from membrane-bound protein, multimerization domains, signal peptide containing proteins and others as needed by the composition in Group II. The composition of Group III is an antagonist of the compositions of Groups 1 and 2; and it does not require binding specifically to the composition of Group 1 as needed by the ligand composition of Group 4. Similar reasons can be applied to polynucleotide compositions encoding the same in Groups 5-7. It is also noted that transgenic animal cell and the transgenic non-human animal in

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Groups 8-9 also have mutually exclusive properties (enhanced vs reduced expression level of a polypeptide of the present invention).

The first methods of uses in Groups 1, 3-6, 8-11 and methods in Groups 12-17 do not share the same technical feature because each method differs from the others in the starting materials and different method steps, as well as different desired end-results (e.g., for producing a polypeptide, for treatment, for screening a candidate compound, for detecting the presence of a transcript). The grouping of these methods is self-explanatory as set forth above.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.**

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN, Ph.D./

Primary Examiner, Art Unit 1633